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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,296	04/20/2004	Michael B. Zemel	31894-202098	2568

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,296	ZEMEL ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10-15* is/are pending in the application.

4a) Of the above claim(s) *5,12,13 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-7, 11, and 14* is/are rejected.

7)☒ Claim(s) *6 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 and 10-15 are pending. Claims 5, 12-13, and 15 are withdrawn as being drawn to non-elected subject matter. **Claims 1-4, 6-7, 10-11, and 14 are under consideration in the instant office action.** Applicants previously cancelled claims 8-9. Receipt and consideration of Applicants remarks/arguments submitted on 5/23/08 and 3/28/08, 1.132 declaration submitted on 3/28/08, and amended claims submitted on 3/28/08 are acknowledged. The office action mailed on March 28, 2008 is vacated.

Election/Restrictions

The species election of coronary heart disease (see office action mailed 1/4/06) is maintained at this time. Claims 5, 12-13, and 15 remain withdrawn from consideration.

Terminal Disclaimer(s)

The terminal disclaimer filed on 2/23/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,384,087 and copending U.S. application No. 10/066,057 has been reviewed and is accepted. The terminal disclaimer has been recorded. It is also noted that a terminal disclaimer over the instant application has been filed and approved in the prosecution of copending application 10/827,307.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/28/08 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 recites that the individual is a human; however, parent claim 1 indicates the individual is a woman. A woman by definition is a human, thus claim 6 fails to further limit claim 1.

Claim 14 is objected to because of the following informalities: the word "coronary artery disease" is misspelled as "coronary artery diseases". There is only one art-recognized coronary artery disease, thus, this appears to be a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 10-11, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' claims 1, 11, and 14 recited the step of administering a sufficient amount of dietary calcium of at least about 773 mg/day, which was introduced by Applicants' October 18, 2006 claim amendments. There is no support in Applicants' specification for calcium intake greater than 1,346 mg ± 113 mg. The range of "at least about 773 mg/day" has no upper limit. Thus, Applicants' specification does not support a range of at least about 773 mg of dietary calcium per day. Applicants' claim 4 recites that the daily calcium intake is at least about 1,000 mg/day. The range of "at least about 1,000 mg/day" has no upper limit. The closest values for the amount of daily calcium administered that are disclosed in Applicants' specification are 1,346 mg ± 113 mg and 773 mg ± 28 mg, neither of which come close to supporting a daily calcium intake amount of "about 1,000 mg/day" or greater than 1,000 mg/day. For these reasons the cited claims contain new matter.

The remaining claims are rejected as depending from a rejected claim.

Claims 1-4, 6, and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of the risk of developing health

problems in a woman suffering from Grade I obesity, does not reasonably provide enablement for the prevention of health problems in a woman suffering from Grade I obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

An analysis based upon the Wands factors is set forth below.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993),. See also *Amgen Inc. v. Chugai Pharm. Co*., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman (230 USPQ 546, 547 (Bd Pat App Int 1986)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Breadth of Claims

Applicants' claim 1 is broad with regards to the health problem that is being "avoided" by practicing the claimed method. "Avoiding" is interpreted as being equivalent to preventing, which is herein interpreted in the absolute sense.

Nature of the invention/State of the Prior Art

The instant invention is drawn to a method of "avoiding health problems" in an individual at risk thereof, wherein the individual is a woman suffering from Grade I obesity and the method comprises in combination during a period of time (a) administering one or more servings of a dairy product comprising administering at least about 773 mg/day of dietary calcium to induce weight loss, reduce weight gain, and/or increase metabolic consumption of adipose tissue in the individual, and (b) maintaining the individual on a restricted calorie diet below ad lib in a range of about 200 kcal/day to about 2,500 kcal/day.

The art recognizes that coronary artery disease is usually caused by the buildup of cholesterol and other fatty materials in the wall of the coronary artery, but that it may also be caused by (1) a coronary spasm of a coronary artery, (2) a birth defect, (3) a viral infection such as Kawasaki disease, (4) systemic lupus erythematosus (lupus), (5) inflammation of the arteries (arteritis), (6) a blood clot that traveled to the heart chamber into one of the coronary arteries, or (7) physical damage from injury or radiation therapy (see Merck Manual Home Edition online article entitled, "Introductions: Coronary Artery Disease"- accessed 9/19/2008 at www.merck.com/mmhe/print/sec03/ch033/ch033a.html). Obesity is also an art-recognized risk factor in developing coronary heart disease. The art also recognizes that cardiovascular disease is the most common cause of death in women (Taggu et al. "Treating cardiovascular disease in women," *Menopause International*, **2007**, *13*, pp 159-164, especially abstract and introduction on pg 159).

Level of One of Ordinary Skill & Predictability/Unpredictability in the Art

The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g. M.D., Ph.D., Pharm. D. or combinations thereof). There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970).

Guidance/Working Examples

Applicants' examples do not demonstrate prevention in the absolute sense. Applicants' Examples 1 and 2 evaluated transgenic murine model (i.e. *agouti* mice) data demonstrating that administration of calcium to mice exhibited, for example, sustained levels of hyperinsulinemia. Applicants' mice models do not demonstrate or suggestion the prevention of coronary artery disease caused by (1) a coronary spasm of a coronary artery, (2) a birth defect, (3) a viral infection such as Kawasaki disease, (4) systemic lupus erythematosus (lupus), (5) inflammation of the arteries (arteritis), (6) a blood clot that traveled to the heart chamber into one of the coronary arteries, or (7) physical damage from injury or radiation therapy. Thus, an ordinary skilled artisan would be expected to undertake unduly burdensome quantity of experimentation to deduce how to prevent all occurrences of health problems in women suffering from Grade I obesity and suffering from coronary artery disease not caused by the buildup of cholesterol or other fatty material.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6,-7, 10-11, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 11, and 14 are indefinite because these claims recite the daily administration of calcium in amounts of at least about 773 mg or at least about 1,000 mg. The phrase "at least about" is indefinite, because it simultaneously claims two different ranges. An ordinary skilled artisan would be unable to ascertain whether the required amount of calcium is at least 773 mg/day or 1,000 mg/day or about 773 mg/day or 1,000 mg/day. Appropriate correction is required. Similarly, the quantity of servings of dairy within a month is also described using an indefinite range of at least about 57 servings in claims 1, 7, 11, and 14.

Claims 1, 7, 11, and 14 are indefinite because these claims recite a step of maintaining an individual on a restricted caloric diet below *ad lib* in a range of about 200 kcal to about 2,500 kcal per day. The term "*ad lib*" means to one's pleasure. Something that is "below one's pleasure" is a subjective term and necessarily renders these claims indefinite.

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-7, 10-11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Science Daily ("Study: Calcium May Curb Weight Gain in Young Women," www.science.daily.com/releases/1999104199042107360 8) in view of Summerbell et al. ("Randomised controlled trial of novel, simple, and well supervised weight reducing diets in outpatients" BMJ 1998 November, 317, pp 1487-1489; 5/27/05 IDS reference) and Eckel ("Obesity and Heart Disease," Circulation, 1997, 96, pp 3248-3250).

Applicant Claims

Applicants claim (1) a method of "avoiding health problems" in an individual at risk thereof, wherein the individual is a woman suffering from Grade I obesity and the method comprises in combination during a period of time (a) administering one or more servings of a dairy product comprising administering at least about 773 mg/day of dietary calcium to induce weight loss, reduce weight gain, and/or increase metabolic consumption of adipose tissue in the individual, and (b) maintaining the individual on a restricted calorie diet below ad lib in a range of about 200 kcal/day to about 2,500 kcal/day.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Science Daily is directed to a **two year study** of the effect of calcium on weight gain. It is disclosed that when overall calorie consumption is accounted for, calcium not only helps to keep weight in check but can be associated specifically with decreases in body fat (paragraph 1). It is disclosed that when **women of the study** consumed a **diet of 1900 calories or less**, those who consumed an average of **1000 mg of calcium per day** showed an **overall decrease in body weight** (paragraph 4 and 5) especially when compared to women those consumed less than 1900 calories but averaged less than 780 mg of calcium per day. The women who averaged less than 780 mg of calcium actually gained body fat mass over the same period (paragraph 4). Women who received their calcium from dairy sources such as milk, yogurt and cheese showed more benefits than those who primarily used non-dairy sources such as vegetables, nuts, beans, and calcium supplements (paragraph 8). It is disclosed that women who consume calcium from dairy

products or who consume at least 1000 mg per day of calcium may reap the most benefit (abstract, second paragraph).

Summerbell et al. is directed to weight reducing diets. The diets of the trial were directed to reducing weight in patents with a body mass index (BMI) greater than 27 (abstract). It is noted that Grade I obesity corresponds to a BMI of 25-29.9. Three diets were administered. Diet 1 was a control. Diet 2 was a milk only diet. Diet three was a milk plus diet, which consisted of milk with the addition of unlimited amount of a single food (page 1488, interventions). It is disclosed that **in the milk only diet patients achieved the highest overall mean weight loss** (page 1489, first paragraph).

Eckel teaches that **comorbidities relating obesity to coronary artery disease (CAD) increases as BMI increases** and that **obesity not only relates to but independently predicts coronary atherosclerosis** (See section entitled, "Obesity and Coronary Heart Disease).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Science Daily does not specify utilizing calcium to induce weight loss in obese women. This deficiency is cured by Summerbell et al. Science daily does not explicitly teach that obesity and the development of CAD are related. This deficiency is cured by Eckel.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily and Summerbell et al. and utilize calcium in a method of inducing weight loss in

an individual suffering from obesity, because both references demonstrate the correlation between diets rich in dietary calcium (e.g. milk only diets) and weight loss. One of ordinary skill in the art would have been motivated to utilize calcium in this type of method because Science Daily indicates that calcium decreases body fat. Therefore, it would have been obvious to utilize calcium in an individual who needs to loose body fat such as an obese person. Furthermore Summerbell et al. indicates that this type of administration has been shown to induce weight loss in obese patients. It would have been obvious to one of ordinary skill in the art to vary the amount of calcium to determine the optimum of amount of calcium for each individual. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made. Regarding the administration of at least 57 servings of dairy per month (instant claims 1, 7, 11, and 14), and the amount of calcium instantly claimed, it is clear that the teachings of Science Daily meet these limitations (at least 1000 mg/day). Therefore, it would have been obvious to one of ordinary skill in the art to determine the appropriate number of servings to consume in order to reach the required daily amount of at least 1000 mg/day. Regarding the implementation of Applicants' claimed method to reduce the incidence of coronary artery disease, Eckell's teachings demonstrate that a correlation

between obesity and coronary artery disease was art-recognized at the time of Applicants' invention. An ordinary skilled artisan would have had a reasonable expectation of successfully reducing the weight of obese women and the incidence or risk of developing CAD by administering said obese women a restricted diet and one or more daily servings of calcium, because the prior art has recognized that diets high in calcium promote weight loss in obese individuals and the risk of developing CAD is correlated with obesity. Thus, it would have been prima facie obvious to prescribe a diet high in calcium to obese women to reduce their risk and/or incidence of CAD, because diets high in calcium were art-recognized as promoting weight loss in obese individuals and obesity was art-recognized as being related to the development of CAD. Common sense clearly indicates that, by definition, obese individuals constitute a patient population that is in need of weight loss. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-7, 10-11, and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of 1-5, 7-10, 12-23 and 25-26 copending Application No. 10/827,297 (copending '297).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope. Copending '297 claims a method of regulating the body weight of an individual comprising the steps of (a) providing the individual with information disclosing that consuming dietary calcium and/or dairy products is associated with one or more health effects selected from loss and/or reduced gain of weight and/or fat, and/or metabolic consumption of adipose tissue, and (b) providing the individual with a dietary plan for consuming products containing an effective amount of dietary calcium and/or dairy products sufficient to induce the one or more health effects.

The instant application claims a method of avoid health problems in an individual at risk thereof due to excess body weight and/or an excess of body fat, the individual suffering form at least Grade I obesity, comprising in combination during a period of time: administer to the individual one or more servings of a dairy product comprising a sufficient amount of dietary calcium of at least about 773 mg per day to induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue in the individual, and maintaining the

individual on a restricted caloric diet below ad lib in a range of about 200 kcal to about 2500 kcal per day, wherein the individual is a women and the one or more servings is at least about 57 servings of dairy per month.

Copending '297 does not claim providing an individual with information disclosing that consuming dietary calcium is associated with one or more heath effects. However, to practice the invention of the instant application, one would necessarily have to be provided with the information that consuming calcium products is associated with one or more heath effects as the method of the instant application is directed to administering calcium to avoid health problems. One of ordinary skill would have to have been informed of calcium's benefit in order to practice the method of the instant application. Therefore, the scope of the claims of the instant application and copending '297 overlap and are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 11, and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8 and 24 of copending Application No. 10/827,353 (copending '353) in view of Eckel ("Obesity and Heart Disease," Circulation, 1997, 96, pp 3248-3250). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed methods are suggested by the dietary plan described in the instructions included in the food package claimed in copending '353, which is targeted towards women. The primary difference between the claims of the instant application and those of copending '353 is that the claims of copending

'353 recite a food package, whereas the claims of the instant application recite methods of avoiding health problems. This difference, however, is rendered obvious because the food package claimed in copending '353 includes instructions that explicitly direct an obese woman to (a) ingest one or more servings of a calcium product comprising at least about 773 mg of calcium per day, (b) restricting caloric intake ad lib below a range of about 200 kcal to about 2,500 kcal/day, wherein the one or more servings are at least about 57 servings of dairy per month. It is noted that at the time of Applicants' invention the correlation between obesity and coronary artery disease (CAD) was art-recognized (see the teachings of Eckel set forth above). Furthermore, it is noted that many of the metabolic results recited in Applicants' claims are also described in the food package claimed in copending '353 (see claims 7-8) of copending '353. Thus, the claims of the instant application represent nothing more than the logical extension of following the instructions contained in the food package claimed in '353 and the methods of the instant application merely obtain the results also described in the food package of copending '353 or reasonably suggested by the knowledge of the prior art (Eckel). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1, 11, and 14 *prima facie* obvious over 1, 6-8 and 24 of copending Application No. 10/827,353 (copending '353) in view of Eckel ("Obesity and Heart Disease," Circulation, 1997, 96, pp 3248-3250).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-4, 6-7, 10-11, and 14 are rejected. Claims 6 and 14 are objected. Claims 5, 12-13, and 15 remain withdrawn from consideration. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
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